

REMARKS

Claims 1-17, 20 and 25-28 remain pending in the application, wherein claims 1, 12, 14 and 25 have been amended. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the foregoing amendments and the following remarks.

The Office Action provisionally rejects claims 1-7, 9, 11-13, 14, 15, 20, 25 and 28 on the grounds of nonstatutory double patenting as being unpatentable over claims 1, 9 and 11-16 of copending Application No. 10/651,671. In making this rejection, the Office Action alleges that the invention claimed in the '671 application is a species of the generic invention recited in the claims of the present application. As evidence of this, the Office Action recites the more specific structure of the tensioning device of the '671 application. However, the claims of the present application are not directed to a tensioning device, but to a suture separation and organization device having specific structural features that are not found in any of the claims of the '671 application. Because the Office Action fails to address the limitations of the present claims relating to the suture separation and organization device, the Office Action fails to state a *prima facie* obviousness-type double patenting rejection. In fact, the claims at issue recite specific features that are not suggested by the simple recitation of a "suture strand separator" in claims 9 and 11 of the '671 application.

While the Office Action cites *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir 1993) for the proposition that a "generic invention is 'anticipated' by [a] 'species'", the Office Action presents no case law or argument that a species is anticipated by or obvious over a genus. Because the claims of the present application define very specific species of the broadly generic "suture strand separator" of claims 9 and 11 of the '671 application, *In re Goodman* does not apply. Moreover, the statement in the Office Action that "the application claims are anticipated by the '671 application claims" is clearly in error since the claims of the present application define specific aspects of a suture separation and organization device that are simply not found in any claims of the '671 application. Thus, the underlying legal and factual bases for applying the double patenting rejection are both in error.

Finally, because the obviousness-type double patenting rejection is merely provisional, Applicants are not required to address the rejection at this time.

The Office Action rejects claims 1-12, 14-17 and 25-27 as being anticipated by WO 01/85042 to Venturini et al. (which can be seen in US 6,749,611), and claims 13 and 20 as being obvious over Venturini et al. in view of US 5,713,897 to Goble et al. In making these rejections, the Office Action asserts that "Venturini et al. discloses a suture separator". This assertion is without merit. According to Venturini et al., this patent discloses and claims "a bone screw useful for fastening external splints, as applied to a fractured limb by orthopedic surgery in order to stabilize the bone fracture." Col. 1, lines 8-10; claim 1. Venturini et al. teaches nothing with respect to separating and organizing sutures. Accordingly, Venturini et al. is not aware of the problem that is solved by the present invention and is therefore nonanalogous art. One of skill in the art, when confronted with the problem associated with tensioned sutures that may block a bone tunnel would not consult the teachings of Venturini et al. to solve this problem. That the bone screw of Venturini et al. has some features that are arguably, but only vaguely, similar to features of one of the embodiments of the present invention is beside the point. The fact that Venturini et al. does not even understand the problem of organizing tensioned sutures, let alone propose a solution to this unrecognized problem, means that Venturini et al. is likely nonanalogous art.

While it is true that nonanalogous art can be cited if it anticipates every feature of a claim, the Office Action fails to show that Venturini et al. teaches every element recited in the claims. Because the bone screw of Venturini et al. includes shallow indentations (or "flats") that have been argued to correspond to the claimed features, Applicants previously amended the claims to add specific functional limitations that cannot be met by the Venturini et al. device, such as being able to actually maintain tensioned sutures in a desired spaced apart relationship. Indeed, the Office Action admits that "it may be true the recesses of Venturini may not be able to separate the sutures after a certain load is applied to the suture". The Office Action then argues that "it is not clearly claimed how applicant's recesses would prevent the same problem". Page 6. In other words, the Office Action takes the position that functional language has no independent limiting aspect beyond the specifically claimed structural features. That is clearly a misreading of applicable regulations and law governing how claims are to be interpreted.

According to MPEP § 2173.05(g), "[a] functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients)." Thus, MPEP § 2173.05(g) clearly states that functional language may

take the place of specific structural features that provide that function. In other words, it is perfectly acceptable for a recited function to replace, or stand in as proxy to, a specific structure. Indeed, 35 U.S.C. § 112, paragraph six, explicitly permits the recitation of a functional limitation to the complete exclusion of any structure (*i.e.*, the function can entirely take the place of the structure):

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

(Emphasis added.) Thus, a claim may recite some structure plus an additional limiting function that further limits the structure, or it may simply recite a function that stands as a proxy for structure, in order to distinguish over a prior art device that is not able to perform the recited function. To anticipate a claim reciting a means-plus-function limitation, or a limitation that recites some structure plus additional function, the prior art device must necessarily provide the function, either explicitly or inherently.

The claims as previously presented all recite a suture separation and organization device that includes means or structure that are specifically required to be able to perform the function of separating and organizing tensioned suture strands extending away from a bone tunnel and reliably maintaining the tensioned suture strands in a desired spaced-apart orientation on either side of the bone tunnel in order that such tensioned suture strands do not inadvertently slip out and move towards each other so as to block insertion of an interference screw therebetween. The Office Action admits that "it is true the recesses of Venturini may not be able to separate the sutures after a certain load is applied to the sutures". Because Venturini et al. admittedly fails to teach or suggest a device that is able to perform the claimed function according to the claims, the Office Action fails to make a *prima facie* claim of anticipation or obviousness.

To make a *prima facie* anticipation rejection, the PTO must show where every limitation is taught in a single reference, either literally or inherently. In this case, not only does the Office Action fail to show that the bone screw of Venturini et al. inherently provides the claimed suture separation function, the Office Action admits that it probably does not. Moreover, because Venturini et al. is nonanalogous art, as it is a bone screw rather than a suture separation and

organizing device, it would not have been obvious from the teachings of Venturini et al. how to modify the admittedly deficient bone screw device to perform the function of reliably maintaining tensioned sutures in a desired spaced apart orientation. Because Venturini et al. is not even aware of the problem associated with tensioned suture strands, Venturini et al. clearly cannot provide any motivation to modify the bone screw device to solve this unknown (and irrelevant) problem from the viewpoint of Venturini et al.

Moreover, one of skill in the art would not have been motivated to combine Venturini et al. with Goble et al. in the manner urged in the Office Action. Whereas Goble et al. discloses a graft tensioning device, Venturini et al. discloses a bone screw that has no applicability to the device or procedure disclosed in Goble et al. To say that Venturini et al. suggests the use of the disclosed bone screw as a suture separator and that it would therefore have been obvious to combine Venturini et al. with Goble et al. is based purely on hindsight, using the present application as a guide. Only the present application is aware of the need to organize tensioned sutures. Neither Goble et al. nor Venturini et al. are aware of this need and therefore cannot be understood as providing a solution to this unknown and irrelevant (to Goble et al. and Venturini et al.) problem. To say that Venturini et al. "teaches a suture separator" is to overlay the teachings of the present application over the nonanalogous teachings of Venturini et al. Thus, any motivation that may flow from this assertion is pure hindsight since the basis for this motivation would come solely from the present application. According to MPEP §2143, the motivation to combine or modify a reference must be found in the prior art and cannot come from applicant's own disclosure.

In conclusion, the claims as previously amended are neither anticipated by nor obvious over the bone screw of Venturini et al., alone or in combination with any other art of record. Moreover, in an effort to advance prosecution, Applicants have amended the claims to further emphasize differences between the claimed suture separation and organization devices and the bone screw of Venturini et al.

Claims 1 and 14 were amended to specifically claim the environment in which the claimed suture separation and organization devices are used, namely, "joint repair surgery in which a soft tissue graft is placed within a bone tunnel, anchored at one end, and tensioned through application of tension by a graft tensioning device to a plurality of sutures attached to an initially free end of the tissue graft, wherein the tensioned suture strands emerge from the bone

tunnel and initially block insertion of an interference screw to anchor the soft tissue graft within the bone tunnel, wherein the tensioned suture strands are moved apart by a suture separation and organization device in a desired spaced-apart relationship on either side of the bone tunnel in order to facilitate insertion of the interference screw between the tensioned strands and into the bone tunnel." Venturini et al. discloses a bone screw but not joint repair surgery and a suture separation and organization device that is specifically adapted to provide the claimed function of separating and organizing a plurality of tensioned sutures.

Claim 1 was further amended to specify that the "attachment means for removably attaching said body means to spaced apart guide posts of a graft tensioning device" also provides the function of "preventing the body means from slipping off the guide posts while tensioned suture strands are maintained in a desired spaced-apart relationship", which function is inherently provided as shown in Figures 7-9. Without the attachment means as now claimed, the device of claim 1 would not be able to provide the function of maintaining the tensioned sutures in a desired spaced apart relationship as the body would be free to slip off the guide posts in response to the tensioned sutures. Because the "attachment means" limitation is defined in terms of its function under 35 U.S.C. § 112, sixth paragraph, for a prior art reference to anticipate claim 1, it must disclose a device that necessarily performs the recited function of the "attachment means". It does not appear that the shallow "flats" of Venturini et al. can provide this function, as opposed to the generally deeper, narrower and more rounded recesses of the embodiment shown in Figures 7-8 of the present application, or the passageways of the embodiment shown in Figures 9-10 of the present application. The recesses and passageways shown in Figures 7-10 comprise "corresponding structure" referred to in 35 U.S.C. § 112, sixth paragraph. According to 35 U.S.C. § 112, sixth paragraph, such structures can be defined functionally rather than structurally. Unless the prior art necessarily performs the claimed function, claim 1 is not anticipated under 35 U.S.C. § 102.

Applicants note that the recited "means for separating and organizing" recited in claim 1 is also written in mean-plus-function format and invokes the provisions of 35 U.S.C. § 112, sixth paragraph. As such, unless the prior art necessarily performs this additional function, claim 1 is not anticipated under 35 U.S.C. § 102 for this additional reason. In fact, the Office Action admits that the Venturini et al. probably fails to provide this function. That is the exact opposite of establishing that it necessarily provides this function, as required by MPEP § 2112 for

establishing inherency when viewed in light of 35 U.S.C. § 112, sixth paragraph. Thus, claim 1 is clearly patentable over Venturini et al., and the Office Action has failed to establish *prima facie* anticipation or obviousness of this claim.

Claim 14 does not invoke 35 U.S.C. § 112, sixth paragraph, because it recites structure in addition to function. Nevertheless, the functional limitations must be considered according to MPEP § 2173.05(g). Because the Office Action admits that Venturini et al. fails to provide the recited function of the "spaced-apart suture retention recesses or protrusions" of claim 14, claim 14 is clearly patentable over Venturini et al., and the Office Action has failed to establish *prima facie* anticipation or obviousness of this claim for this reason alone. Moreover, it is unlikely that the "flats" of Venturini et al. would be able to provide the function associated with the "plurality of attachment passages or recesses", which are exemplified by the recesses having a deeper and narrower draw in Figures 7 and 8 of the present application. For this additional reason, claim 14 is clearly patentable over Venturini et al., and the Office Action has failed to establish *prima facie* anticipation or obviousness.

Finally, claim 25 defines a device that includes a combination of structural features that are simply not found in Venturini et al., even assuming the loose interpretation given in the Office Action. As stated above, Venturini et al. admittedly fails to provide the recited function of the claimed suture separation and organization device. Moreover, claim 25 as amended claims a minimum of four "suture retention recesses or protrusions" (*i.e.* first and second *pairs*), at least one passage for mating with a corresponding post of a graft tensioning device (Figures 9-10), and a passageway or recess through which an interference screw can be inserted during joint repair surgery. That makes a total of six of such structures. The five "flats" of the bone screw of Venturini et al. shown in Figure 1 cannot meet the six structural requirements of claim 1. Nor would there have been any motivation to modify Venturini et al. to include every feature of claim 25 in order to provide the claimed functions because Venturini et al. is entirely unaware of the need to separate and organize sutures in the manner provided by the device of claim 25. Venturini et al. discloses a bone screw, not a suture separation and organization device.

In conclusion, Applicants submit that the Application is currently in allowable form. In the event that the Examiner finds any remaining impediment to a prompt allowance of this

application that may be clarified through a telephone interview or which may be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 4th day of August 2006.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. M. Gynn', written in a cursive style.

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